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37 C.F.R. § 1.8

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April 30, 2002

Date

  
Shelley P.M. Fussey

**PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Arun K. Roy, Yan Lavrovsky, Rakesh K. Tyagi, Chung S. Song, Bandana Chatterjee and Shuo Chen

Serial No.: 10/009,420

Filed: December 4, 2001

For: Estrogen Receptor Site-Specific Ribozymes and Uses Thereof for Estrogen Dependent Tumors

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: 4003.002300

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record in the present case. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R §§ 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Assistant Commissioner is hereby authorized to deduct said fees from Williams, Morgan & Amerson, P.C., Deposit Account No. 50-0786/4003.002300.

Respectfully submitted,



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Date: April 30, 2002

Form PTO-1449 (modified)

Atty. Docket No.

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Serial No.

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List of Patents and Publications for Applicant's  
INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

Applicant

Roy et al.

#3

Filing Date:

December 4, 2001

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U.S. Patent Documents

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Foreign Patent Documents

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Other Art

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### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	5,834,440	November 10, 1998	Goldenberg <i>et al.</i>	514	44	
	A2	5,525,468	June 11, 1996	McSwiggen	435	6	
	A3	5,496,698	March 5, 1996	Draper <i>et al.</i>	435	6	

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 00/74485	December 14, 2000	PCT			
	B2	WO 99/54459	October 28, 1999	PCT			

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	Amarzguioui and Prydz, "Hammerhead Ribozyme Design and Application," <i>CMLS</i> , 54:1175-1202, 1998.
	C2	Branch, "A Good Antisense Molecule is Hard to Find," <i>TIBS</i> , 23:45-50, 1998.
	C3	Chen <i>et al.</i> , "Catalytic Cleavage of the Androgen Receptor Messenger RNA and Functional Inhibition of Androgen Receptor Activity by a Hammerhead Ribozyme," <i>Mol. Endocrinol.</i> , 12(10):1558-1566, 1998.
	C4	Chen, "Molecular Strategies for Selective Inhibition of Androgen Receptor Gene Expression," <i>A Dissertation presented to the Faculty of The University of Texas Graduate School of Biomedical Sciences at San Antonio in partial fulfillment of the requirements for the Degree of Doctor of Philosophy in Cellular and Structural Biology, March, 1997</i> ; Also, Volume 58/03-B of Dissertation Abstracts International, page 1103, 1997.
	C5	Chen and Roy, "Specific Inactivation of the Androgen Receptor Messenger RNA by a Hammerhead Ribozyme," <i>Premier Event in 10<sup>th</sup> International Congress of Endocrinol.</i> , 10:87, 1996.
	C6	Cotton and Birnstiel, "Ribozyme Mediated Destruction of RNA <i>in vivo</i> ," <i>EMBO J.</i> , 8(12):3861-3866, 1989.

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Other Art

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### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C7	Forster and Symons, "Self-Cleavage of Plus and Minus RNAs of a Virusoid and a Structural Model for the Active Sites," <i>Cell</i> , 49:211-220, 1987.
	C8	Haseloff and Gerlach, "Simple RNA Enzymes with New and Highly Specific Endoribonuclease Activities," <i>Nature</i> , 334:585-591, 1988.
	C9	James, "Towards Gene-Inhibition Therapy; A Review of Progress and Prospects in the Field of Antiviral Antisense Nucleic Acids and Ribozymes," <i>Antisense Nucleic Acids and Ribozymes</i> , 2(4):191-214, 1991.
	C10	Klefstrom <i>et al.</i> , "c-Myc Induces Cellular Susceptibility to the Cytotoxic Action of TNF- $\alpha$ ," <i>EMBO J.</i> , 13(22):5442-5450, 1994.
	C11	Kobayashi <i>et al.</i> , "Reversal of Drug Sensitivity in Multidrug-Resistant Tumor Cells by an MDR1 (PGY1) Ribozyme," <i>Cancer Research</i> , 54:1271-1275, 1994.
	C12	Lavrovsky <i>et al.</i> , "Ribozyme-mediated Cleavage of the Estrogen Receptor Messenger RNA and Inhibition of Receptor Function in Target Cells," <i>Mol. Endocrinol.</i> , 13(6):925-934, 1999.
	C13	L'Huillier <i>et al.</i> , "Efficient and Specific Ribozyme-Mediated Reduction of Bovine $\alpha$ -Lactalbumin Expression in Double Transgenic Mice," <i>Proc. Natl. Acad. Sci. USA</i> , 93:6698-6703, 1996.
	C14	Marshall, "Gene Therapy's Growing Pains," <i>Science</i> , 269:1050-1055, 1995.
	C15	Marshall, "Gene Therapy on Trial," <i>Science</i> , 288:951-957, 2000.
	C16	Milner <i>et al.</i> "Selecting Effective Antisense Reagents on Combinatorial Oligonucleotide Arrays," <i>Nature Biotechnology</i> , 15:537-541, 1997.
	C17	Pyle, "Ribozymes: A Distinct Class of Metalloenzymes," <i>Science</i> , 261:709-714, 1993.
	C18	Barver <i>et al.</i> , "Ribozymes as Potential Anti-HIV-1 Therapeutic Agents," <i>Science</i> , 247:1222-1225, 1990.
	C19	Scanlon <i>et al.</i> , "Ribozyme-Mediated Cleavage of c-fos mRNA Reduces Gene Expression of DNA Synthesis Enzymes and Metallothionein," <i>Proc. Natl. Acad. Sci. USA</i> , 88:10591-10595, 1991.
	C20	Stull and Szoka, "Antigene, Ribozyme and Aptamer Nucleic Acid Drugs: Progress and Prospects," <i>Pharmaceutical Research</i> , 12(4):465-483, 1995.

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<b>List of Patents and Publications for Applicant's</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <small>(Use several sheets if necessary)</small>		<b>Applicant</b> <b>Roy et al.</b>	
<small>U.S. Patent &amp; Trademark Office</small> <small>MAY 06 2002</small> <small>912</small>		<b>Filing Date:</b> <b>December 4, 2001</b>	<b>Group:</b>
<b>Patent Documents</b> <i>See Page 1</i>		<b>Foreign Patent Documents</b> <i>See Page 1</i>	<b>Other Art</b> <i>See Page 1 - 3</i>

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C21	Suzuki <i>et al.</i> , "Adenovirus-Mediated Ribozyme Targeting of HER-2neu Inhibits <i>in vivo</i> Growth of Breast Cancer Cells," <i>Gene Therapy</i> , 7:241-248, 2000.
	C22	Turley <i>et al.</i> , "Vitamin E Succinate Induces Fas-Mediated Apoptosis in Estrogen Receptor-Negative Human Breast Cancer Cells," <i>Cancer Research</i> , 57:881-890, 1997.
	C23	Uhlenbeck, "A Small Catalytic Oligoribonucleotide," <i>Nature</i> , 328:596-600, 1987.
	C24	International Search Report for PCT/US00/15243, mailed October 4, 2000.

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